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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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**Complete if Known**

Application Number	09/963,920
Filing Date	September 26, 2001
First Named Inventor	Barany et al.
Art Unit	1639
Examiner Name	P. Ponnaluri
Attorney Docket Number	19603/3356 (CRF D-1595F)


**U.S. PATENT DOCUMENTS**

Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	U.S. Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
ADS	1	US-5,104,792	04-14-1992	Silver et al.	
ADS	2	US-5,512,441	04-30-1996	Ronai	
ADS	3	US-6,156,501	12-05-2000	McGall et al.	
ADS	4	US-6,852,487	02-08-2005	Barany et al.	
ADS	5	US-5,932,711	08-03-1999	Boles et al.	
ADS	6	US-5,868,136	02-09-1999	Fox et al.	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>4</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>2</sup> (if known)				
ADS	7	EP 0 624 643 A2	11-17-1994	Fraiser et al.		
ADS	8	EP 0 628 640 A1	12-14-1994	Walker et al.		
ADS	9	WO 95/35390	12-28-1995	Zhang		
ADS	10	WO 97/31256	08-28-1997	Barany et al.		
ADS	11	EP 0 357 011 A2	08-30-1989	Laffler et al.		
ADS	12	EP 0 387 696 A2	03-08-1990	McMahan et al.		

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
ADS	13	"Nucleic Acid Hybridisation: A Practical Approach," B.D. Hames & S.J. Higgins eds., IRL Press, Oxford, Washington D.C., pp. 5-7 (1985)	
ADS	14	HSUIH et al., "Novel, Ligation-Dependent PCR Assay for Detection of Hepatitis C Virus in Serum," <i>J. Clin. Microbiol.</i> 34(3):501-507 (1996)	
ADS	15	ZEBALA et al., "Characterization of Steady State, Single-Turnover, and Binding Kinetics of the <i>TaqI</i> Restriction Endonuclease," <i>J. Biol Chem.</i> 267(12):8097-8105 (1992)	
ADS	16	ZEBALA et al., "Implications for the Ligase Chain Reaction in Gastroenterology," <i>J. Clin. Gastroenterol.</i> 17(2):171-175 (1993)	
ADS	17	ZIRVI et al., "Improved Fidelity of Thermostable Ligases for Detection of Microsatellite Repeat Sequences Using Nucleoside Analogs," <i>Nucleic Acids Res.</i> 27(24):e41 (1999)	
ADS	18	ZIRVI et al., "Ligase-Based Detection of Mononucleotide Repeat Sequences," <i>Nucleic Acids Res.</i> 27(24):e40 (1999)	
ADS	19	"Acrylamide" <i>Wikipedia Encyclopedia</i> , Retrieved from the internet at <a href="http://en.wikipedia.org/wiki/Acrylamide">http://en.wikipedia.org/wiki/Acrylamide</a> on September 15, 2005	
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PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

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<b>Substitute for form 1449A/PTO</b> <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	09/963,920
Sheet 1 of 4				Filing Date	September 26, 2001
				First Named Inventor	Barany et al.
				Art Unit	1639
				Examiner Name	P. Ponnaluri
				Attorney Docket Number	19603/3356 (CRF D-1595F)

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ADS	1	US-5,035,996	07-30-1991	Hartley	
ADS	2	US-5,314,809	05-24-1994	Erlich et al.	
ADS	3	US-5,407,798	04-18-1995	Martinelli et al.	
ADS	4	US-5,418,149	05-13-1995	Gelfand et al.	
ADS	5	US-5,536,649	07-16-1996	Fraiser et al.	
ADS	6	US-5,593,840	01-14-1997	Bhatnagar et al.	
ADS	7	US-5,731,171	03-24-1998	Bohlander	
ADS	8	US-5,800,984	09-01-1998	Vary	
ADS	9	US-5,876,924	03-02-1999	Zhang et al.	
ADS	10	US-5,912,148	06-15-1999	Eggerding	
ADS	11	US-5,942,391	08-24-1999	Zhang et al.	
ADS	12	US-6,569,647	05-27-2003	Zhang et al.	

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		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>2</sup> (if known)				
ADS	13	WO 96/06190	02-29-1996	Eggerding		

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ADS	14	BIANCALANA et al., "Moderate Instability of the Trinucleotide Repeat in Spino Bulbar Muscular Atrophy," <i>Hum. Mol. Genet.</i> 1(4):255-258 (1992)	
ADS	15	BRONNER et al., "Mutation in the DNA Mismatch Repair Gene Homologue <i>hMLH1</i> is Associated with Hereditary Non-Polyposis Colon Cancer," <i>Nature</i> 368:258-261 (1994)	

Examiner Signature	Date Considered
	2-27-06

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)				Application Number	09/963,920
				Filing Date	September 26, 2001
				First Named Inventor	Barany et al.
				Group Art Unit	1639
				Examiner Name	P. Ponnaluri
Sheet	2	of	4	Attorney Docket Number	19603/3356 (CRF D-1595F)

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ADS	16	CAIRNS et al., "Homozygous Deletions of 9p21 in Primary Human Bladder Tumors Detected by Comparative Multiple Polymerase Chain Reaction," <i>Cancer Res.</i> 54:1422-1424 (1994)	
ADS	17	CAWKWELL et al., "Frequency of Allele Loss of <i>DCC</i> , <i>p53</i> , <i>RBI</i> , <i>WT1</i> , <i>NF1</i> , <i>NM23</i> , and <i>PC/MCC</i> in Colorectal Cancer Assayed by Fluorescent Multiplex of Polymerase Chain Reaction," <i>Br. J. Cancer</i> 70(5):813-818 (1994)	
ADS	18	CELI et al., "A Rapid and Versatile Method to Synthesize Internal Standards for Competitive PCR," <i>Nucleic Acids Research</i> 21(4):1047 (1993)	
ADS	19	CHUNG et al., "Evidence for a Mechanism Predisposing to Intergenerational CAG Repeat Instability in Spinocerebellar Ataxia Type I," <i>Nat. Genet.</i> 5:254-258 (1993)	
ADS	20	DENG et al., "An Improved Method of Competitive PCR for Quantitation of Gene Copy Number," <i>Nucleic Acids Research</i> 21(20):4848-4849 (1993)	
ADS	21	FISHEL et al., "The Human Mutator Gene Homolog <i>MSH2</i> and its Association with Hereditary Nonpolyposis Colon Cancer," <i>Cell</i> 75:1027-1038 (1993)	
ADS	22	GONZALEZ-ZULUETA et al., "Microsatellite Instability in Bladder Cancer," <i>Cancer Res.</i> 53:5620-5623 (1993)	
ADS	23	HAN et al., "Genetic Instability in Pancreatic Cancer and Poorly Differentiated Type of Gastric Cancer," <i>Cancer Res.</i> 53:5087-5089 (1993)	
ADS	24	IMBERT et al., "Origin of the Expansion Mutation in Myotonic Dystrophy," <i>Nat. Genet.</i> 4:72-76 (1993)	
ADS	25	IONOV et al., "Ubiquitous Somatic Mutations in Simple Repeated Sequences Reveal a New Mechanism for Colonic Carcinogenesis," <i>Nature</i> 363:558-561 (1993)	
ADS	26	KOIDE et al., "Unstable Expansion of CAG Repeat in Hereditary Dentatorubral-Pallidoluysian Atrophy (DRPLA)," <i>Nat. Genet.</i> 6:9-13 (1994)	
ADS	27	KREMER et al., "Mapping of DNA Instability at the Fragile X to a Trinucleotide Repeat Sequence p(CCG) <sub>n</sub> ," <i>Science</i> 22:1711-1714 (1991)	

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ADS	28	LEACH et al., "Mutations of a <i>mutS</i> Homolog in Hereditary Nonpolyposis Colorectal Cancer," <i>Cell</i> 75:1215-1225 (1993)	
ADS	29	MAO et al., "Microsatellite Alterations As Clonal Markers for the Detection of Human Cancer," <i>Proc. Natl. Acad. Sci. USA</i> 91:9871-9875 (1994)	
ADS	30	MAO et al., "Molecular Detection of Primary Bladder Cancer by Microsatellite Analysis," <i>Science</i> 271:659-662 (1996)	
ADS	31	MERLO et al., "Frequent Microsatellite Instability in Primary Small Cell Lung Cancer," <i>Cancer Res.</i> 54:2098-2101 (1994)	
ADS	32	NAWROZ et al., "Allelotype of Head and Neck Squamous Cell Carcinoma," <i>Cancer Res.</i> 54:1152-1155 (1994)	
ADS	33	NEWTON et al., "The Production of PCR Products with 5' Single-Stranded Tails Using Primers That Incorporate Novel Phosphoramidite Intermediates," <i>Nucleic Acids Research</i> 21(5):1155-1162 (1993)	
ADS	34	NILSSON et al., "Padlock Probes: Circularizing Oligonucleotides for Localized DNA Detection," <i>Science</i> 265:2085-2088 (1994)	
ADS	35	ORR et al., "Expansion of an Unstable Trinucleotide CAG Repeat in Spinocerebellar Ataxia Type 1," <i>Nat. Genet.</i> 4:221-226 (1993)	
ADS	36	PAPADOPOULOS et al., "Mutation of a <i>mutL</i> Homolog in Hereditary Colon Cancer," <i>Science</i> 263:1625-1629 (1994)	
ADS	37	PARK et al., "Detection of HCV RNA Using Ligation-Dependent Polymerase Chain Reaction in Formalin-Fixed, Paraffin-Embedded Liver Tissue," <i>Am. J. Pathology</i> 149(5):1485-1491 (1996)	
ADS	38	PEINADO et al., "Isolation and Characterization of Allelic Losses and Gains in Colorectal Tumors by Arbitrarily Primed Polymerase Chain Reaction," <i>Proc. Natl. Acad. Sci. USA</i> 89:10065-10069 (1992)	
ADS	39	PELTOMÄKI et al., "Microsatellite Instability is Associated with Tumors That Characterize the Hereditary Non-Polyposis Colorectal Carcinoma Syndrome," <i>Cancer Res.</i> 53:5853-5855 (1993)	

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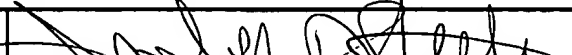
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ADS	40	RADFORD et al., "Allelotyping of Ductal Carcinoma <i>in Situ</i> of the Breast: Deletion of Loci on 8p, 13q, 16q, 17p and 171," <i>Cancer Res.</i> 55:3399-3406 (1995)	
ADS	41	RISINGER et al., "Genetic Instability of Microsatellites in Endometrial Carcinoma," <i>Cancer Res.</i> 53:5100-5103 (1993)	
ADS	42	RUPPERT et al., "Evidence for Two Bladder Cancer Suppressor Loci on Human Chromosome 9," <i>Cancer Res.</i> 53:5093-5095 (1993)	
ADS	43	SYVÄNEN et al., "Identification of Individuals by Analysis of Biallelic DNA Markers, Using PCR and Solid-Phase Minisequencing," <i>Am. J. Hum. Genet.</i> 52:46-59 (1993)	
ADS	44	THE HUNTINGTON'S DISEASE COLLABORATIVE RESEARCH GROUP, "A Novel Gene Containing a Trinucleotide Repeat That is Expanded and Unstable on Huntington's Disease Chromosomes," <i>Cell</i> 72:971-983 (1993)	
	45	<del>THIBODEAU et al., "Microsatellite Instability in Cancer of the Proximal Colon," <i>Science</i> 260:816-819 (1993)</del> no copy	
ADS	46	VAN DER RIET et al., "Frequent Loss of Chromosome 9p21-22 Early in Head and Neck Cancer Progression," <i>Cancer Res.</i> 54:1156-1158 (1994)	
ADS	47	WEGMÜLLER et al., "Combination of Oligonucleotide Ligation and PCR to Detect Point Mutations," (unpublished)	
ADS	48	WEISSENBAACH et al., "A Second-Generation Linkage Map of the Human Genome," <i>Nature</i> 359:794-801 (1992)	

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